

I. AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the present application.

Listing of Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1. (Original): Amino acid particles in which a sample of the particles has a bulk density not more than 0.1 g/cm^3 .

Claim 2. (Original): Amino acid particles according to claim 1, in which a sample of the particles has a bulk density not more than 0.05 g/cm^3 .

Claim 3. (Original): Amino acid particles having a mass median aerodynamic diameter (MMAD) not more than $5\mu\text{m}$.

Claim 4. (Original): Amino acid particles being in the form of flakes having a thickness of not more than $0.5\mu\text{m}$.

Claim 5. (Original): Amino acid particles according to claim 4 in which the flakes having a thickness of not more than 100 nm.

Claim 6. (Previously presented): Amino acid particles according to claim 1, in which the amino acid is leucine.

Claim 7. (Previously presented): A powder for use in a dry powder inhaler, the powder including active material and amino acid particles according to claim 1.

Claim 8. (Original): A powder according to claim 7, in which the powder includes not more than 20% by weight of amino acid based on the weight of the powder.

Claim 9. (Previously presented): A powder according to claim 8, in which the powder includes not more than 10% by weight of amino acid based on the weight of the powder.

Claim 10. (Currently amended): A powder ~~according to claim 7,~~ for use in a dry powder inhaler, said powder including active material, particles of a diluent, and amino acid particles in which a sample of the amino acid particles has a bulk density of not more than 0.1 g/cm³, the powder ~~further including.~~

Claim 11. (Original): A powder according to claim 10, in which the diluent includes a crystalline sugar.

Claim 12. (Previously presented): A powder according to claim 10, in which the diluent has a particle size such that at least 90% by weight of the diluent particles have a particle size not more than 10 μ m.

Claim 13. (Previously presented): A powder according to claim 10, in which the diluent has a particle size such that at least 90% by weight of the diluent particles have a particle size not less than 50 μ m.

Claim 14. (Previously presented): A powder according to claim 10, in which the diluent has a fine particle portion having a particle size such that at least 90% by weight of the particles of the fine particle portion have a particle size not more than 10 μ m and a coarse particle portion having

a particle size such that at least 90% by weight of the particles of the coarse particle portion have a particle size not less than $50\mu\text{m}$.

Claim 15. (Original): A powder according to claim 14, in which the fine particle portion and coarse particle portion comprise the same material.

Claim 16. (Previously presented): A powder according to claim 14, in which the powder includes not more than 5% by weight of the fine particle portion based on the weight of the powder.

Claim 17. (Previously presented): A powder according to claim 14, in which the powder includes not more than 95% by weight of the coarse particle portion based on the weight of the powder.

Claim 18. (Currently amended): A dry powder inhaler, the inhaler containing powder, wherein said powder includes active material and amino acid particles in which a sample of the amino acid particles has a bulk density of not more than 0.1 g/cm^3 according to claim 7.

Claim 19. (Currently amended): A method of preparing particles of amino acid ~~as claimed in claim 3~~, the method including the step of forming solid amino acid particles from a vapor or from a solvent, the method being such that the particles are formed while being suspended in a gas flow, said particles having a mass median aerodynamic diameter (MMAD) not more than $5\mu\text{m}$.

Claim 20. (Currently amended): A method of preparing particles of amino acid ~~as claimed in claim 1~~, the method including the step of condensing amino acid vapor to form solid amino acid particles, wherein a sample of said amino acid particles has a bulk density not more than 0.1 g/cm^3 .

Claim 21. (Previously presented): A method according to claim 19, in which particles of amino acid are formed by aerosol condensation.

Claim 22. (Previously presented): A method according to claim 20, in which the method includes the steps of

- a) heating the amino acid so that the amino acid forms a vapor;
- b) mixing the amino acid vapor with cool air to form a cloud of condensed amino acid particles; and
- c) collecting the condensed particles.

Claim 23. (Previously presented): A method according to claim 20, the method including the step of heating the amino acid particles to a temperature of at least 150°C at ambient pressure.

Claim 24. (Cancelled)

Claim 25. (Original): A method according to claim 19, in which the method includes the step of spray drying to form solid particles of amino acid.

Claim 26. (Original): A method according to claim 25, in which the material to be dried comprises amino acid in solution.

Claim 27. (Cancelled)

Claim 28. (Cancelled)

Claim 29. (Previously presented) A method according to claim 19, in which the method is such that the MMAD of the solid amino acid particles produced is not more than 10 μ m.

Claims 30. - 38. (Cancelled)

This response is being submitted within 30 (thirty) from the date of the Notice of Non-Compliant Amendment. Accordingly, no fee is believed due. If it is determined that any fees are due, Commissioner is hereby authorized to charge any deficiencies to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Cary S. Kappel
Reg. No. 36,561

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940